

<b>PROCESS:</b> Product Specifications	<b>ISSUE DATE:</b> 09.03.2022	<b>DOC NO:</b> 081240BBI <b>Q-pulse Ref. No.:</b> CT-PRDS22
<b>TITLE:</b> Hyaluronidase (BBI Grade)	<b>REVISION:</b> 7	<b>PAGE:</b> 1 of 1
<b>AUTHORISED:</b> Laboratory Supervisor		<b>APPROVED:</b> SQR Leader

Product Code: 081240BBI

EC No.: 3.2.1.35

EDQM Certificate no.: R1-CEP 2001-085-Rev 02

Aspect	Description	Units	Limits	Method
<b>Form</b>	White to yellowish, amorphous salt-free, freeze-dried powder	N/A	N/A	N/A
<b>Preparation</b>	Bovine Testes	N/A	N/A	N/A
<b>Activity</b>	Assay	U/mg material	≥500	BP6.2.2-WI204
<b>Additional Data</b>	Loss on Drying (LOD)	N/A	≤5%	BP6.2.2-WI27
	Identification	N/A	Positive	BP6.2.2-WI140
	Solubility	N/A	Clear	BP6.2.2-WI105
	pH (3 mg / ml aqueous solution)	N/A	4.5-7.5	BP6.2.2-WI117
	<u>E. coli</u>	Cfu/g	0	BP6.2.3-WI64
	<u>Salmonella</u>	Cfu/10g	0	BP6.2.3-WI66
	<u>Pseudomonas aeruginosa</u>	Cfu/g	0	BP6.2.3-WI63
	Total Aerobic Microbial Count	Cfu/g	1000 cfu/g	BP6.2.3-WI49
Total Combined Yeast & Mould Count	Cfu/g	1000 cfu/g	BP6.2.3-WI70	
<b>Retest Date</b>	Re-assay	Months	36	N/A
<b>Storage</b>	Storage Temperature	°C	-20	N/A
<b>Transit</b>	Storage in Transit	°C	Ambient	N/A
<b>Packaging</b>	<ul style="list-style-type: none"> <li>Amber glass bottles for samples</li> <li>Polytainers</li> </ul>	N/A	N/A	N/A
<b>Labels</b>	<u>Large Label</u> <ul style="list-style-type: none"> <li>Name of product</li> <li>Product Code</li> <li>Lot Number</li> <li>Net Weight</li> <li>Manufacture Date</li> <li>Retest Date</li> <li>Storage Temperature</li> <li>Storage in Transit</li> <li>"Material for research &amp; further manufacture only"</li> </ul>	N/A	N/A	N/A
	<u>Small label</u> <ul style="list-style-type: none"> <li>Name of Product</li> <li>Product Code</li> <li>Lot No.</li> <li>Net Weight</li> <li>Manufacture Date</li> <li>Retest Date</li> <li>Storage Temperature</li> <li>Storage in Transit</li> <li>"Material for research &amp; further manufacture only"</li> </ul>	°C °C	-20 Ambient	N/A
<b>Samples</b>	Retention	1 g 10 g	8 2	N/A
	Quality Control	1 g	2	
	Microbiology	1 g 10 g	2 1	
<b>Special Instructions</b>	None	N/A	N/A	N/A